# Exhibit 1

**CDC FREEDOM OF INFORMATION ACT REQUEST**

**VIA ONLINE PORTAL** June 13, 2024

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

Re: *Protocol & Data Sets for 1989 Hepatitis B Vaccine Study (IR#10016B)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**") and Mississippi Medical Professionals for Informed Consent ("**MMPIC**"). On behalf of ICAN and MMPIC, please provide the following records to foia@sirillp.com in electronic form:

> **The protocol and all data sets for the study titled, "Prevalence, incidence, and progression of human immunodeficiency virus infection in homosexual and bisexual men in hepatitis B vaccine trials, 1978-1988" published by the American Journal of Epidemiology in December 1989, attached hereto as Attachment A.**
>
> **Information helpful to fulfilling the request: Responsive records should include, but not be limited to, the following:**
>
> **(1) The total number of trial participants who contracted human immunodeficiency virus (HIV) and who received at least one dose of the hepatitis B vaccine.**
> **(2) The total number of trial participants who contracted HIV and who received the placebo only.**
> **(3) The HIV infection rate by number of doses among trial participants by year.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety, other medical treatments, environmental pollutants and toxins, and overall health choices, and to provide the public with information needed in order to give informed consent. As part of its mission, ICAN actively investigates and disseminates scientifically based health information regarding the safety of vaccines, other medical treatments, environmental pollutants

and toxins, and governmental activities for free through its website,[1] a weekly health news and talk show,[2] and through press events and releases. The HighWire website has approximately 3.4 million weekly visitors. On X (formerly known as Twitter), The High Wire has approximately 190,000 followers and 1 to 2.5 million impressions in a 28-day period. On Rumble, The HighWire has approximately 83,000 followers and growing. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act ("**FOIA**"). ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of government programs and any potential effects of same on public health. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

MMPIC is a not-for profit organization comprised of medical professionals throughout the state of Mississippi. MMPIC's mission is to raise public awareness about vaccine safety, other medical treatments, and overall health choices, and to provide the public with information needed in order to give informed consent. MMPIC is seeking the information in this FOIA request to allow it to contribute to the public understanding of government programs and actions and any potential effects of those programs and actions on public health. The information MMPIC is requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN and MMPIC reserve all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN and MMPIC may immediately take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

[1] https://www.icandecide.org/.

[2] https://thehighwire.com/.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (240) 732-6737 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Sincerely,

*/s/ Aaron Siri*

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# Attachment A

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# PREVALENCE, INCIDENCE, AND PROGRESSION OF HUMAN IMMUNODEFICIENCY VIRUS INFECTION IN HOMOSEXUAL AND BISEXUAL MEN IN HEPATITIS B VACCINE TRIALS, 1978–1988

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LYNDA S. DOLL,[2] HAROLD W. JAFFE,[2] AND GEORGE W. RUTHERFORD[1]

**Hessol, N. A. (AIDS Office, Dept. of Public Health, San Francisco, CA 94102), A. R. Lifson, P. M. O'Malley, L. S. Doll, H. W. Jaffe, and G. W. Rutherford. Prevalence, incidence, and progression of human immunodeficiency virus infection in homosexual and bisexual men in hepatitis B vaccine trials, 1978–1988. *Am J Epidemiol* 1989;130:1167–75.**

**Between 1978 and 1980, 359 hepatitis B seronegative homosexual and bisexual men were recruited from the San Francisco municipal sexually transmitted disease clinic for hepatitis B vaccine trials. Of the 359 participants, 320 (89%) consented to have their stored blood samples tested for human immunodeficiency virus antibodies. The prevalence of human immunodeficiency virus infection in these 320 vaccine trial participants rose from 0.3% in 1978 to 50.9% in 1988. The annual incidence of human immunodeficiency virus infection showed that seroconversion peaked in 1980–1982, dropped significantly in 1983, and has remained low. Men < 30 years old on entry into the study seroconverted earlier in the epidemic and had higher incidence rates than men 30 years or older ($p = 0.07$). No statistical difference in seroconversion rates was found for other demographic variables. Using a Kaplan-Meier survival curve of the cumulative proportion of men without acquired immunodeficiency syndrome by duration of human immunodeficiency virus infection, an estimated 39% (95% confidence interval 27%–51%) will develop acquired immunodeficiency syndrome within 9.2 years of infection. Cox proportional hazard stepwise analysis showed no correlation between age at seroconversion, race, or year of seroconversion and progression to acquired immunodeficiency syndrome.**

**acquired immunodeficiency syndrome; homosexuality; HIV**

In the United States, homosexual and bisexual men represent the exposure category with the largest number of reported cases of acquired immunodeficiency syndrome. Homosexual and bisexual men constitute 68 percent of all adults with acquired immunodeficiency syndrome (including 7 percent homosexual intravenous drug users) as of May 1989 (1). Studies of human immunodeficiency virus infection in homosexual and bisexual men living in large cities throughout the United States have

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The authors thank Lyn Cannon and the Research Branch staff for data collection, Dr. Stephen C. Hadler for his work with studies of hepatitis B, Dr. Robert H. Byers for his statistical assistance, and Dr. William W. Darrow for his early work on acquired immunodeficiency syndrome.

generally shown high prevalence rates but currently low incidence rates (2), suggesting that most new infections occurred before the mid 1980s. Although many studies have indicated the proportion of study participants who were human immunodeficiency virus seropositive on entry, few studies have been able to document when seroconversion actually occurred. Similarly, most studies in homosexual men have looked at disease progression in persons who were infected with human immunodeficiency virus at enrollment, but few studies have been able to estimate the rate of human immunodeficiency virus disease progression following a known date of seroconversion.

During the late 1970s and early 1980s, nationwide serologic studies were conducted on the prevalence, incidence, and prevention of sexually transmitted hepatitis B virus in cohorts of homosexual and bisexual men (3–8). In San Francisco, 6,697 homosexual and bisexual men were screened for these studies at the San Francisco municipal sexually transmitted disease clinic.

Early in the acquired immunodeficiency syndrome epidemic a disproportionate number of acquired immunodeficiency syndrome patients diagnosed in San Francisco appeared to be among the 6,697 cohort members originally screened for hepatitis B studies. This included six of the first 10 cases and nearly half of the cases reported in 1981. Epidemiologic data indicated that risk groups for acquired immunodeficiency syndrome and hepatitis B virus infection were similar and that sexual or drug-use behaviors that increased the risk for hepatitis B virus transmission also increased the risk for acquired immunodeficiency syndrome (9, 10). Recognizing the importance of the original hepatitis B cohort, the San Francisco Department of Public Health and the Centers for Disease Control began acquired immunodeficiency syndrome follow-up studies in this cohort in late 1983 (11). This presentation analyzes the prevalence, incidence, and progression of human immunodeficiency virus infection in the subgroup of men from this cohort who participated in hepatitis B vaccine trials.

## Materials and methods

### *Study population*

The San Francisco City Clinic (for sexually transmitted diseases) screened 6,697 homosexual and bisexual men between 1978 and 1980 for studies of the prevalence, incidence, and prevention of sexually transmitted hepatitis B. Among cohort members, approximately 25 percent tested negative to the hepatitis B serologic markers when first screened. When the hepatitis B vaccine trial began in 1980, 359 hepatitis B virus seronegative men were randomized into a double-blind, placebo-controlled trial in which half the participants received Merck hepatitis B virus vaccine and half received a placebo vaccine. Participants were vaccinated between April 1980 and July 1981. In October 1981 the treatment and placebo codes were broken when efficacy was proven, and those men originally assigned to the placebo group who had not developed hepatitis B were offered vaccination between October 1981 and May 1982. Blood was drawn at the time of each injection and at one, two, four, six, eight, and 12 months from the date of the first dose and then at approximately six-month intervals. All unused sera were frozen and stored. Long-term follow-up of vaccine trial participants is still being conducted.

### *Study protocol*

Beginning in 1983, we asked all 359 men who participated in the hepatitis B vaccine trials to consent to participate in acquired immunodeficiency syndrome follow-up studies. After development of the human immunodeficiency virus antibody test, stored sera were tested for human immunodeficiency virus antibodies by an enzyme-linked immunoabsorbent assay and confirmed, when sufficient serum was

available, by either Western blot or immunofluorescence assay. Each year we also asked vaccine trial participants for consent to draw additional blood for serologic testing, an interview regarding behavioral and environmental risk factors for human immunodeficiency virus infection and acquired immunodeficiency syndrome, and an examination by a physician for clinical manifestations of human immunodeficiency virus infection and human immunodeficiency virus disease.

### *Data analysis*

We estimated the date of seroconversion as the midpoint between the last negative and first positive specimen for participants with ≤24 months between serum samples. For participants who were positive on entry or had >24 months between the last negative and first positive specimen, we derived a probability estimate for date of seroconversion based on the men with ≤24 months between serum samples (12). We calculated duration of infection as the time from the date of seroconversion to May 15, 1989, or, for men with acquired immunodeficiency syndrome, to the date of acquired immunodeficiency syndrome diagnosis. We defined acquired immunodeficiency syndrome as the presence of disease that met the current Centers for Disease Control surveillance case definition and was determined either by history and physical examination or by cross-matching with San Francisco and national acquired immunodeficiency syndrome surveillance records by date of birth and soundex code, an alphanumeric code based on last name.

To determine the cumulative prevalence and annual incidence of human immunodeficiency virus infection, BMDP1L actuarial life-table analysis was performed (13). Additional life-table analyses were performed examining the association of age (<30 years old on entry into the study or ≥30 years), ethnicity (white or nonwhite (including Latinos)), and years of education (<16 years of schooling or ≥16 years on first interview) with human immunodeficiency virus seroconversion. Differences in seroconversion rates within the demographic groups were assessed for significance using a generalized Wilcoxon test for equality.

We used the BMDP1L Kaplan-Meier time to progression analysis to estimate the proportion of human immunodeficiency virus-infected men who will develop acquired immunodeficiency syndrome (13). To examine the effects of age at seroconversion, race, and year of seroconversion on progression to acquired immunodeficiency syndrome while controlling for duration of human immunodeficiency virus infection, we performed Cox proportional hazard stepwise analysis using BMDP2L (13). Only those vaccine trial participants who had dates of seroconversion within a known 24-month interval or who were positive on entry were included in the Kaplan-Meier and Cox analyses.

## RESULTS

Of the 359 participants in the hepatitis B vaccine trial, 320 (89 percent) consented to have their stored serum specimens tested for human immunodeficiency virus antibodies. Among the 39 men who were not tested for human immunodeficiency virus antibodies, 22 declined and 17 were lost to follow-up. Of the 320 tested, 162 (51 percent) were human immunodeficiency virus antibody negative on all serum specimens, 20 (6 percent) were human immunodeficiency virus antibody positive on all serum specimens, and 138 (43 percent) seroconverted between the time of their first and last serum samples. Of the 138 seroconverters, 80 percent had 12 months or less between their last negative and first positive serum specimen, and 85 percent had ≤24 months (table 1).

The cumulative prevalence of human immunodeficiency virus infection for all 320 hepatitis B vaccine trial participants rose from 0.3 percent in 1978 to 50.9 percent in 1988 (figure 1). The annual incidence of

human immunodeficiency virus infection in seronegative men showed that seroconversion peaked in 1981 and 1982, dropped in 1983, and has remained low (figure 2).

The incidence of human immunodeficiency virus infection in seronegative men by age groups showed that men less than 30 years old on entry into the cohort seroconverted earlier in the epidemic and had higher incidence rates than men 30 years old or older on entry into the cohort ($p = 0.07$). No differences in seroconversion rates were found for ethnicity (white vs. nonwhite) or years of education (<16 years vs. ≥16 years) (table 2). The mean age at enrollment for this cohort was 30 years with a range of 18 to 57 years.

A total of 135 men who had less than 25 months between a human immunodeficiency virus-negative and human immunodeficiency virus-positive serum sample, or were seropositive on entry into the cohort, were included in a Kaplan-Meier survival curve of the cumulative proportion of men with acquired immunodeficiency syndrome by duration of infection. Of these 135 men, 41 were known to have developed acquired immunodeficiency syndrome prior to May 15, 1989 (table 3). From analysis of these 135 men, an estimated 5 percent (95 per-

TABLE 1

*Time between the last human immunodeficiency virus antibody-negative and first human immunodeficiency virus antibody-positive serum specimen among seroconverters, hepatitis B vaccine trial, San Francisco, 1978–1988*

| Time between last negative and first positive specimen | No. (%) | Cumulative percent |
|---|---|---|
| 0–12 months | 110 (80) | 80 |
| 13–24 months | 7 (5) | 85 |
| 25–36 months | 10 (7) | 92 |
| 37–48 months | 6 (4) | 96 |
| ≥49 months | 5 (4) | 100 |
| Total | 138 | |

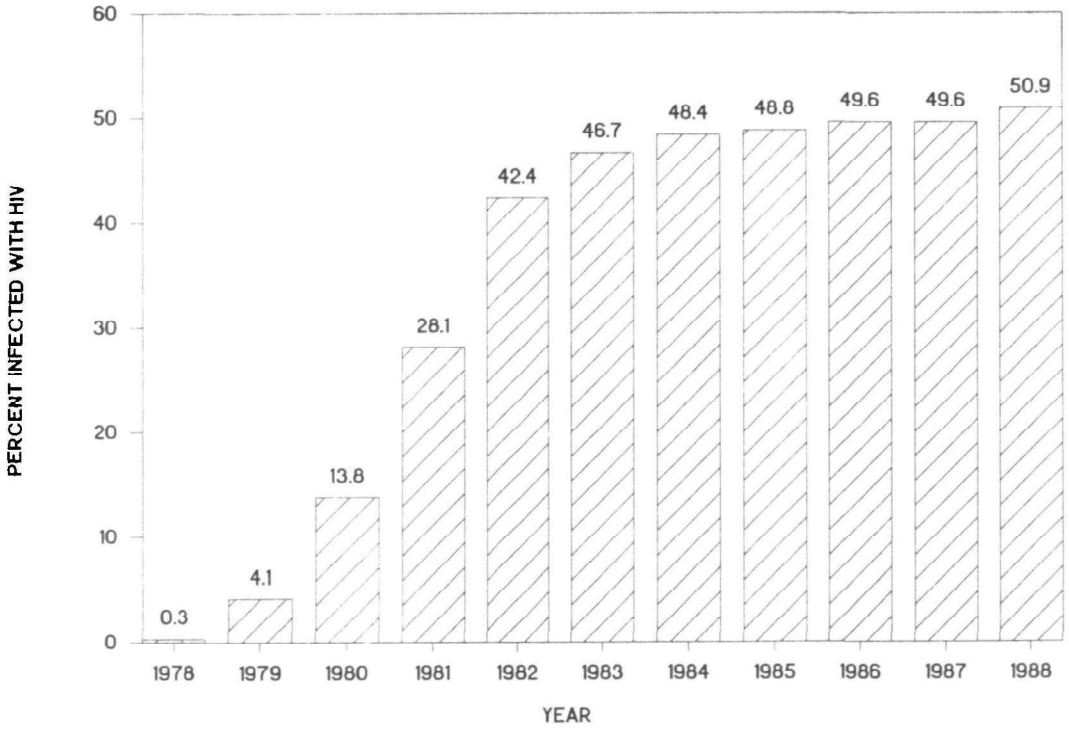


FIGURE 1. Annual cumulative prevalence of human immunodeficiency virus infection among 320 hepatitis B vaccine trial participants, San Francisco, 1978–1988.

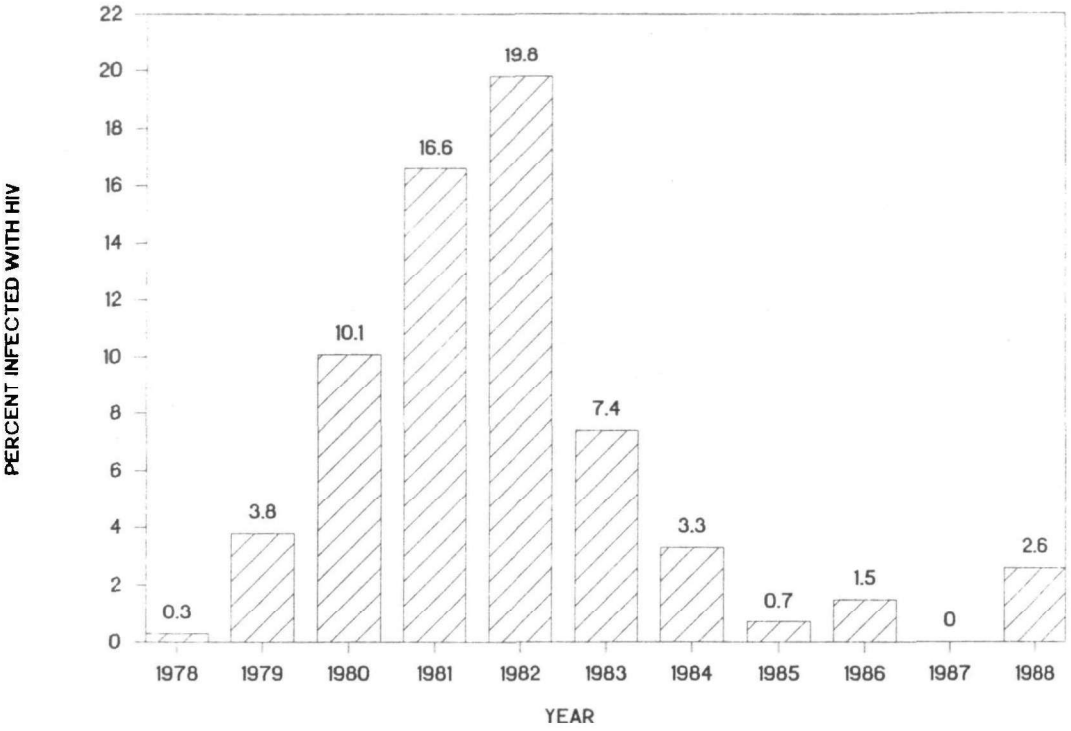


FIGURE 2. Annual incidence of human immunodeficiency virus infection among 320 hepatitis B vaccine trial participants, San Francisco, 1978–1988.

TABLE 2

*Incidence of human immunodeficiency virus infection among susceptible men by demographic groups, hepatitis B vaccine trial, San Francisco, 1978–1988*

| Variable (no.) | Incidence per 100 person-years | Wilcoxon *p* value |
|---|---|---|
| Age | | |
| <30 years old on entry (146) | 8.1 | |
| ≥30 years old on entry (168) | 6.2 | 0.07 |
| Ethnicity | | |
| White (285) | 7.3 | |
| Nonwhite (18) | 5.7 | 0.47 |
| Years of education | | |
| <16 (103) | 6.2 | |
| ≥16 (181) | 6.2 | 0.30 |

TABLE 3

*Incidence of acquired immunodeficiency syndrome (AIDS) by number of years after estimated seroconversion, hepatitis B vaccine trial, San Francisco, 1978–1988*

| No. of years after seroconversion | No. diagnosed with AIDS |
|---|---|
| 0–1 | 0 |
| 1–2 | 2 |
| 2–3 | 5 |
| 3–4 | 10 |
| 4–5 | 5 |
| 5–6 | 7 |
| 6–7 | 6 |
| 7–8 | 4 |
| 8–9 | 1 |
| >9 | 1 |
| Total | 41 |

cent confidence interval (CI) 1–9 percent) will develop acquired immunodeficiency syndrome within three years of infection, 13 percent (95 percent CI 7–19 percent) within four years, 17 percent (95 percent CI 10–24 percent) within five years, 23 percent (95 percent CI 16–30 percent) within six years, 28 percent (95 percent CI 20–36 percent) within seven years, 33 percent (95 percent CI 24–42 percent) within eight years, 36 percent (95 percent CI 26–46 percent) within nine years, and 39 percent (95 percent CI 27–51 percent) will

develop acquired immunodeficiency syndrome within 9.2 years of infection (figure 3). Virtually identical results were obtained when the 20 men who were positive for human immunodeficiency virus on their first serum specimen were excluded from the Kaplan-Meier analysis (data not shown).

These 135 men with well approximated dates of seroconversion to human immunodeficiency virus were then analyzed for progression to acquired immunodeficiency syndrome using a Cox proportional hazards stepwise model. When controlling for duration of infection with human immunodeficiency virus, no correlation was found between age at seroconversion ($p = 0.5$), ethnicity ($p = 0.6$), or year of seroconversion ($p = 0.2$) and progression to acquired immunodeficiency syndrome.

## Discussion

The stored serum samples from homosexual and bisexual men that were originally collected for studies of sexually transmitted hepatitis B in San Francisco have provided essential information on the prevalence, incidence, and progression of human immunodeficiency virus infection. However, the results of this study need to be interpreted cautiously before they are applied to other populations at risk for human immunodeficiency virus infection. All the men in this study were recruited from a municipal sexually transmitted disease clinic and, because they may have been more sexually active, they may have been at higher risk for exposure to human immunodeficiency virus than other homosexual and bisexual men. Additionally, if other

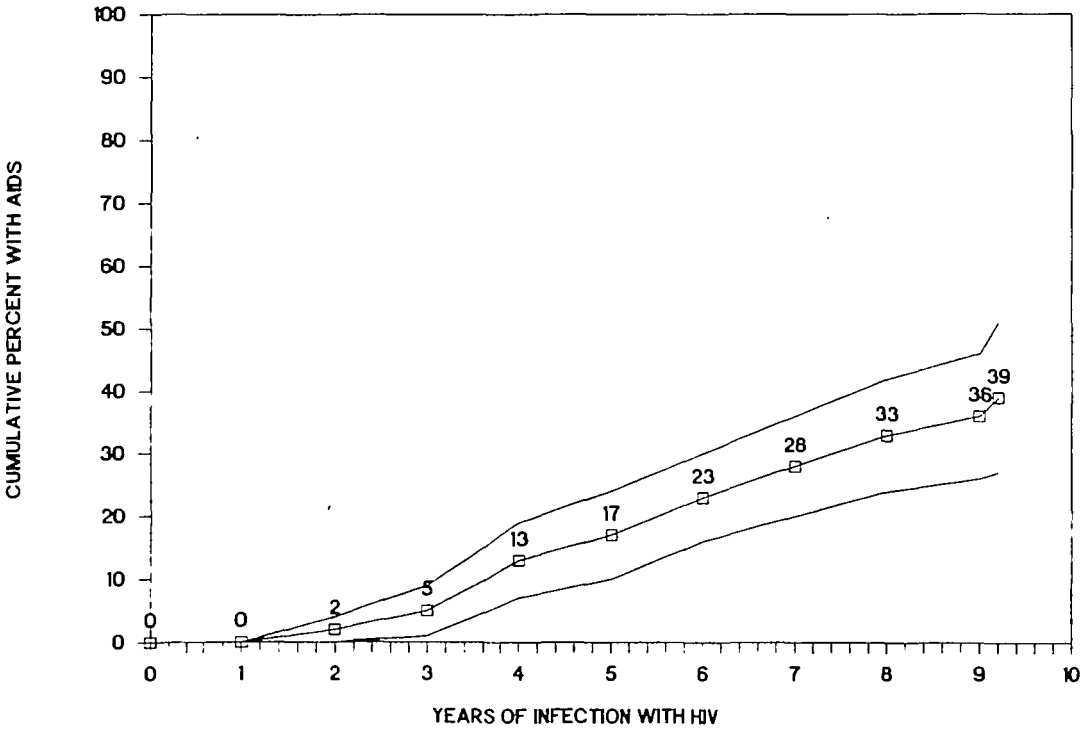


FIGURE 3. Kaplan-Meier survival curve of the cumulative proportion of men with acquired immunodeficiency syndrome by duration of human immunodeficiency virus infection among 135 hepatitis B vaccine trial participants, San Francisco, 1978–1988. The upper and lower line represent the upper and lower 95 percent confidence interval, respectively.

sexually transmitted diseases act as cofactors for human immunodeficiency virus infection (14–16), these men may again be at higher risk for infection with human immunodeficiency virus.

On the other hand, all the vaccine trial participants were hepatitis B virus seronegative on entry into the trial and had less exposure to human immunodeficiency virus and other sexually transmitted diseases than the cohort of hepatitis B seropositive homosexual and bisexual men seen at City Clinic. Participants in the hepatitis B vaccine trial have a lower estimated prevalence of human immunodeficiency virus infection (51 percent in 1988) than the estimated prevalence in all other men screened at the San Francisco City Clinic (73 percent in 1986) (12). Additionally, the 1987 seroprevalence of human immunodeficiency virus infection in two other homosexual and bisexual male cohort studies in San Francisco is estimated at 50 percent in the San Francisco Men's Health study, a neighborhood based study in 19 high risk for acquired immunodeficiency syndrome census tracts (17), and 41 percent in the San Francisco General Hospital cohort, a neighborhood based study of all census tracts (P. Bacchetti, San Francisco General Hospital, personal communication, 1988). Therefore, the estimated prevalence of human immunodeficiency virus infection for the hepatitis B vaccine trial participants may be representative of other homosexual and bisexual men in San Francisco.

Seroconversion rates in vaccine trial participants for the recent years are low, with no one seroconverting in 1987 and three men seroconverting in 1988. Behavioral data show that the decline in incidence of human immunodeficiency virus infection is paralleled by a decline in high risk sexual behaviors (18), such as receptive anal intercourse with ejaculation and without condom use (19). Data from both the San Francisco Men's Health study and the San Francisco General Hospital cohort also suggest that most incident human immunodeficiency virus infections occurred before 1984; since then, the rate of acquisition of new human immunodeficiency virus infection has been extremely low (17, 20).

In a study of 378 homosexually active men recruited for studies of hepatitis B virus in New York City, the cumulative prevalence of human immunodeficiency virus infection increased from 6.6 percent in 1979 to 43.7 percent in 1984 (21). The annual seroconversion rates among susceptible men during these years ranged from 5.5 percent to 10.6 percent, with the highest rates in 1982 and 1983. In Amsterdam, a study of 685 homosexual men who participated in hepatitis B vaccine trials showed that the cumulative prevalence of human immunodeficiency virus infection increased from a weighted 2.2 percent in 1980 to 39 percent in 1987 (22). The estimated human immunodeficiency virus attack rate was 3 percent in 1981, rose to 8.8 percent in 1984, and decreased gradually to zero percent in 1987.

Younger men, less than 30 years of age on entry into the study, seroconverted earlier in the epidemic than older men, although this difference was of borderline significance. Men less than 30 years of age on entry into the study also reported higher numbers of male sexual partners with whom they engaged in receptive anal intercourse. We found no differences in seroconversion rates for ethnicity or years of education, but this may be because our study group included very few nonwhites and over 50 percent of the participants had college degrees.

A number of studies have prospectively evaluated cohorts of human immunodeficiency virus-infected homosexual and bisexual men for progression to acquired immunodeficiency syndrome (23, 24). In general, these studies show that the risk for acquired immunodeficiency syndrome in human immunodeficiency virus-infected men increases over time. However, estimates of the likelihood of progression have varied (25). The most likely explanation for

differences in the rate of progression is that the risk of disease for human immunodeficiency virus-infected persons is not constant over time. Therefore, the duration of human immunodeficiency virus infection at the time of recruitment will directly impact a person's rate of progression following enrollment in a study. In this analysis, dates of seroconversion can be well approximated, and any bias due to duration of human immunodeficiency virus infection at enrollment can be controlled for. Data on progression to acquired immunodeficiency syndrome following seroconversion from the Multicenter AIDS Cohort Study of homosexual men show similar progression, with 22 percent developing acquired immunodeficiency syndrome within five years of infection (26).

Various cofactors may alter progression to development of acquired immunodeficiency syndrome once a person is infected (27). We found no correlation with age at seroconversion, ethnicity, or year of seroconversion and progression to acquired immunodeficiency syndrome. However, the homogeneity of this cohort, with respect to age, ethnicity, and years of schooling, may limit the ability to detect such differences. Receipt of the hepatitis B vaccine does not change one's risk of developing acquired immunodeficiency syndrome (28–30), and serologic response to the vaccine was not predictive of subsequent human immunodeficiency virus infection (30).

There is evidence that without any therapy or treatment, the proportion of human immunodeficiency virus-infected persons who will develop acquired immunodeficiency syndrome will continue to increase (31). It is not possible to say, based on current data, whether everyone infected with human immunodeficiency virus will develop acquired immunodeficiency syndrome. Over the past few years there has been an intensive search for drugs and vaccines to curb the growing epidemic. Antiviral therapy, antimicrobial prophylaxis, and possibly vaccines and health enhancing behaviors may significantly alter the progression from infection with human immunodeficiency virus to acquired immunodeficiency syndrome. As yet we have been unable to detect any effect of Zidovudine (AZT) or other antiviral therapies on progression to acquired immunodeficiency syndrome (26). Additional follow-up and more complete ascertainment of therapeutics and prevention practices in this and other cohorts will be necessary to determine their future effects on disease progression.

## References


1. HIV/AIDS surveillance report. Atlanta, GA: Centers for Disease Control, May 1989:1–16.
2. Centers for Disease Control. Human immunodeficiency virus infection in the United States: a review of current knowledge. MMWR 1987;36 (suppl):22–7.
3. Szmuness W. Large-scale efficacy trials of hepatitis B vaccines in the USA: baseline data and protocols. J Med Virol 1979;4:327–40.
4. Schreeder MT, Thompson SE, Hadler SC, et al. Hepatitis B in homosexual men: prevalence of infection and factors related to transmission. J Infect Dis 1982;146:7–15.
5. Szmuness W, Stevens CE, Harley EJ, et al. Hepatitis B vaccine: demonstration of efficacy in a controlled clinical trial in a high-risk population in the United States. N Engl J Med 1980;303:833–41.
6. Francis DP, Hadler SC, Thompson SE, et al. The prevention of hepatitis B with vaccine: report of the Centers for Disease Control multi-center efficacy trial among homosexual men. Ann Intern Med 1982;97:362–6.
7. Szmuness W, Stevens CE, Zang EA, et al. A controlled clinical trial of the efficacy of the hepatitis B vaccine (Heptavax B): a final report. Hepatology 1981;1:377–85.
8. Hadler SC, Francis DP, Maynard JE, et al. Long-term immunogenicity and efficacy of hepatitis B vaccine in homosexual men. N Engl J Med 1986;315:209–14.
9. Szmuness W, Much MI, Prince AM, et al. On the role of sexual behavior in the spread of hepatitis B infection. Ann Intern Med 1975;83:489–95.
10. Centers for Disease Control. Acquired immune deficiency syndrome (AIDS): precautions for clinical and laboratory staffs. MMWR 1982;31:577–80.
11. Jaffe HW, Darrow WW, Echenberg DF, et al. The acquired immunodeficiency syndrome in a cohort of homosexual males: a 6-year follow-up study. Ann Intern Med 1985;103:210–14.
12. Byers RH Jr, Morgan WM, Darrow WW, et al. Estimating AIDS infection rates in the San Francisco cohort. AIDS 1988;2:207–10.
13. Dixon WJ, ed. BMDP statistical software. Los Angeles, CA: University of California Press, 1985.

14. Plummer F, Cameron W, Simonsen N, et al. Cofactors in male-female transmission of HIV. Presented at the IV International Conference on AIDS, Stockholm, Sweden, June 1988.
15. Cannon RO, Hook EW, Nahmias AJ, et al. Association of herpes simplex virus type 2 with HIV infection in heterosexual patients attending sexually transmitted disease clinics. Presented at the IV International Conference on AIDS, Stockholm, Sweden, June 1988.
16. Holmberg SD, Gerber AR, Stewart JA, et al. Prior HSV-2 infection as a risk factor for HIV infection. Presented at the IV International Conference on AIDS, Stockholm, Sweden, June 1988.
17. Winkelstein W Jr, Samuel M, Padian NS, et al. The San Francisco Men's Health Study. III. Reduction in human immunodeficiency virus transmission among homosexual/bisexual men, 1982–1986. Am J Public Health 1987;76:685–9.
18. Centers for Disease Control. Self-reported changes in sexual behaviors among homosexual and bisexual men from the San Francisco City Clinic cohort. MMWR 1987;36:187–9.
19. Hessol NA, O'Malley PM, Lifson AR, et al. Incidence and prevalence of HIV infection among homosexual and bisexual men, 1978–1988. Presented at the V International Conference on AIDS, Montreal, Canada, June 1989.
20. Moss AR, Bacchetti P, Osmond D, et al. Seropositive for HIV and the development of AIDS or AIDS related condition: three year follow up of the San Francisco General Hospital cohort. Br Med J 1988;296:745–50.
21. Stevens CE, Taylor PE, Zang EA, et al. Human T-cell lymphotropic virus type III infection in a cohort of homosexual men in New York City. JAMA 1986;255:2167–72.
22. Van Griensven GJP, De Vroome EMM, Goudsmit J, et al. Changes in sexual behaviour and the fall in incidence of HIV infection among homosexual men. Br Med J 1989;298:218–21.
23. Goedert JJ, Biggar RJ, Weiss SH, et al. Three-year incidence of AIDS in five cohorts of HTLV-III-infected risk group members. Science 1986; 231:992–5.
24. Lifson AR, Hessol NA, Rutherford GW, et al. The natural history of HIV infection in a cohort of homosexual and bisexual men: clinical manifestations, 1978–1989. Presented at the V International Conference on AIDS, Montreal, Canada, June 1989.
25. Lifson AR, Rutherford GW, Jaffe HW. The natural history of human immunodeficiency virus infection. J Infect Dis 1988;158:1360–7.
26. Muñoz A, Wang MC, Bass S, et al. Acquired immunodeficiency syndrome (AIDS)-free time after human immunodeficiency virus type 1 (HIV-1) seroconversion in homosexual men. Am J Epidemiol 1989;130:530–9.
27. Hessol NA, Barnhart JL, O'Malley PM, et al. The natural history of HIV infection in a cohort of homosexual and bisexual men: cofactors for disease progression, 1978–1989. Presented at the V International Conference on AIDS, Montreal, Canada, June 1989.
28. Centers for Disease Control. Hepatitis B vaccine: evidence confirming lack of AIDS transmission. MMWR 1984;33:685–6.
29. Stevens CE, Taylor PE, Rubenstein P, et al. Safety of the hepatitis B vaccine. N Engl J Med 1985;312:375–6.
30. Buchbinder SP, Hessol NA, Lifson AR, et al. The interaction of HIV and hepatitis B vaccination in a cohort of homosexual and bisexual men. Presented at the V International Conference on AIDS, Montreal, Canada, June 1989.
31. Hessol NA, O'Malley PM, Lifson AR, et al. Projections of the cumulative proportion of HIV-infected men who will develop AIDS. Presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, California, October 1988.